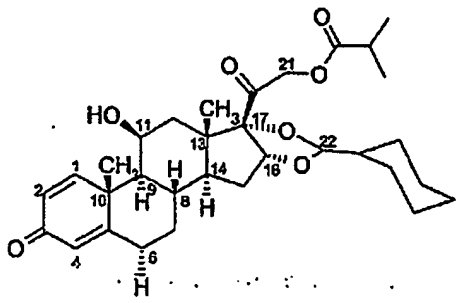
Claims

1. Process for preparing a compound of the formula I



Formula I

in crystalline form, with defined particle size, comprising the steps of

a) preparation of a solution of the compound of the formula I in a suitable water-miscible organic solvent;

b) adding the solution obtained as in a) to water and

c) isolating the precipitate of the compound of the formula I which is formed.

2. Process according to Claim 1, characterized in that the suitable water-miscible organic solvent is an alcohol.

3. Process according to Claim 2, characterized in that the alcohol is selected from the group of methanol, ethanol, N-propanol and isopropanol or mixtures in any mixing ratio thereof.

4. Process according to Claim 3, characterized in that ethanol is involved.

5. Process according to Claim 1, characterized in that acetone, tetrahydrofuran or dimethylformamide is involved.

6. Process according to Claim 1, characterized in that the temperature of the suitable water-miscible organic solvent is in the range from 15°C to 10°C below the boiling point of the solvent.

7. Process according to Claim 6, characterized in that the temperature of the suitable water-miscible organic solvent corresponds to the room temperature at which the process is carried out.

8. Process according to Claim 1, characterized in that the temperature of the water is from 10 to 50°C.

9. Process according to Claim 7, characterized in that the temperature of the water corresponds to the room temperature at which the process is carried out.

10. Process according to Claim 1, characterized in that the compound of the formula I has the chemical name 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11beta, 16alpha (R,S)].

11. Process according to Claim 1, characterized in that the compound of the formula I is substantially in the form of the R epimer.

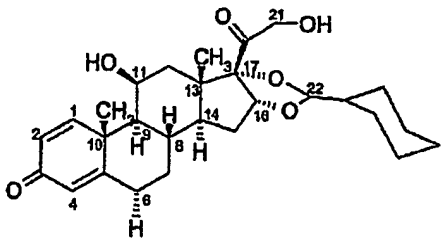
12. Process according to Claim 11, characterized in that the proportion of R epimer in the compound of the formula I is more than 95%.

13. Process according to Claim 11, characterized in that ciclesonide is involved.

14. Process according to Claim 1, characterized in that the precipitate obtained after step c) is subsequently dried.

15. Process for preparing a compound of the formula I according to Claim 1 in crystalline form with defined particle size, comprising the steps of

a) preparing a compound of the formula I by acylation of a compound of the formula II



Formula II

with a suitable acylating agent;

b) crystallizing the compound of the formula I obtained in a) by adding water to a solution of the compound in a suitable water-miscible organic solvent or heating a suspension of the

compound of the formula I in a mixture of a suitable water-miscible organic solvent and water,

c) removing the resulting R epimer-enriched precipitate of the compound of the formula I from the water/solvent mixture;

d) if desired repeating step b);

e) preparing a solution of the compound obtained in c) in a suitable water-miscible organic solvent;

f) adding the solution obtained as in e) to water and

g) isolating the precipitate which has been formed of the compound of the formula I.

16. Process according to Claim 1, where the particle size is characterized by an X_{90} of less than or equal to 10.

17. Process according to Claim 16, where the particle size is characterized by an X_{90} of in the range from 1.8 to 2.0.

18. Process according to Claim 15, where the organic solvents used in steps b) and e) are the same solvents.

19. Compound of the formula I obtainable according to Claim 1 without further micronization step, where the compound is in inhalable form.

20. Compound according to Claim 19, where the particle size of the compound of the formula I has an X_{90} in the range from 1.8 to 2.0.

21. Compound according to Claims 19 or 20, which compound is not in micronized form.

22. Crystalline ciclesonide with a particle size characterized by an X_{90} of less than or equal to 10.

23. Crystalline ciclesonide with a particle size characterized by an X_{90} of in the range from 1.8 to 2.0.

24. Crystalline ciclesonide according to Claims 22 or 23, which ciclesonide is not in micronized form.

25. Pharmaceutical composition comprising a compound according to Claims 19 to 24, which compound is present as solid particles together with pharmaceutically acceptable excipients.

26. Pharmaceutical composition according to claim 25, which is an aqueous suspension of the compound.

27. Pharmaceutical composition according to claim 25, which is a dry powder.